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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/775,517 02/02/01 GRABOWSKI

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026874
FROST BROWN TODD, LLC
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CINCINNATI OH 45202

HM22/1030

EXAMINER

OZGA, B

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 10/30/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/775,517

Applicant(s)

GRABOWSKI ET AL.

Examiner

Brett T Ozga

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-68 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-68 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 56 and 53 are substantial duplicates. If claim 53 were found allowable, claim 56 would need to be cancelled.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 51,53,54,56,58 and 59 are rejected under 35 U.S.C. 102(b) as being anticipated by Rader et al. (FASEB J. vol. 10, 1996, page A233)

The instant application claims a method for providing biologically active lipid hydrolyzing protein or polypeptide, or mixtures thereof, to cells of a mammal having deficiency in biologically active lipid hydrolyzing protein or polypeptide, said method comprising administration into cells a vector comprising and expressing a DNA sequence encoding biologically active lipid hydrolyzing protein or polypeptide, and expressing the DNA sequence in said cells to produce biologically active lipid hydrolyzing protein or polypeptide. Dependent claims further limit by choosing

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lysosomal acid lipase as the biologically active lipid hydrolyzing protein or polypeptide. They further limit by choosing a viral vector (lentivirus, adenovirus, adeno-associated virus and virus-like vectors) as the vector.

Rader et al. teach a method for providing biologically active lysosomal acid lipase, or mixtures thereof, to cells of a human having deficiency in biologically active lysosomal acid lipase, said method comprising administration into cells an adenoviral vector comprising and expressing a DNA sequence encoding biologically active lysosomal acid lipase, and expressing the DNA sequence in said cells to produce biologically active lysosomal acid lipase. (See abstract.)

Claims 19,20,23,28-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Sigma Chemie, product catalog.(1996, Sigma Chemical Co. p. 271)

The instant application claims a method for treatment of atherosclerosis in a mammal comprising administering to said mammal a safe and effective amount of a lipid hydrolyzing protein or polypeptide, or mixtures thereof, sufficient to treat said condition. Dependent claims further limit by having the protein or polypeptide target a receptor site for uptake into lysosomes. They further limit by choosing lysosomal acid lipase as the protein. They further limit by choosing a lipase with more or fewer than six N-linked acetylglycosylation residues and wherein the residues are oligosaccharide-terminated (mannose) They further limit by exogenously producing the protein. The

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claims further limit by placing the protein in a pharmaceutically acceptable carrier and administering orally, parenterally, by injection, intravenous infusion, inhalation, controlled dosage release or intraperitoneal administration.

Sigma Chemical Co. teaches claims a method for treatment of atherosclerosis in a mammal comprising administering to said mammal a safe and effective amount of a pharmaceutical acceptable carrier and an exogenously produced lysosomal acid lipase which targets a receptor site for uptake into lysosomes. They teach the lipase with more or fewer than six N-linked acetylglycosylation residues wherein the residues are mannose-terminated (See p. 271)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rader et al. in view of Du et al. (AM J. HUMAN GENET, vol. 57, 1995 page A178).

Rader et al. teach a method for providing biologically active lysosomal acid lipase, or mixtures thereof, to cells of a human having deficiency in biologically active lysosomal acid lipase, said method comprising administration into cells an adenoviral vector comprising and expressing a DNA sequence encoding biologically active lysosomal acid lipase, and expressing the DNA sequence in said cells to produce biologically active lysosomal acid lipase.

They also teach administering a lipid hydrolyzing protein or polypeptide to catalyze the hydrolysis of cholesteryl esters and triglycerides in the lysosomes of cells.

Rader et al. do not specifically teach administering that lipid hydrolyzing protein or polypeptide to reduce atherosclerotic plaques in a mammal.

Du et al. teach a process for to reduce atherosclerotic plaques in a mammal.

It would have been prima facie obvious for a person of ordinary skill in the art at the time the invention was made to modify the teachings of Rader et al. by the additions of the teachings of Du et al. Rader et al. is already drawn to triglycerides in cells, so to use the lipase of Rader et al. to reduce atherosclerotic plaques would be obvious. Thus, in view of the cited references, the artisan of ordinary skill would have been motivated to have practiced the process as recited in the claims.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brett T Ozga whose telephone number is 7033050634. The examiner can normally be reached on M-F 0530-1500, 2nd Wednesday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 7033084743. The fax phone numbers for the organization where this application or proceeding is assigned are 7033084242 for regular communications and 7033053014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 7033080196.

BTO
October 30, 2001



SANDRA E. SAUCIER
PRIMARY EXAMINER